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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Shunichi Bandoh

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APEX JURIS, PLLC

12360 LAKE CITY WAY NORTHEAST

SUITE 410

SEATTLE, WA 98125

EXAMINER

RAPP, CHAD

ART UNIT

PAPER NUMBER

2121

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,182	Applicant(s) BANDOH ET AL.	
	Examiner CHAD RAPP	Art Unit 2121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/21/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. Claims 1-7 are presented for examination.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 1, line 2 “the use” should be changed to “a use”. There is insufficient antecedent basis for this limitation in the claim.

As to claim 1, lines 17-18 “said three dimension image” should be changed to “a three dimension image”. There is insufficient antecedent basis for this limitation in the claim.

As claim 2, line 7 “the finite element” should be changed to “a finite element”. There is insufficient antecedent basis for this limitation in the claim.

As claim 3, line 7 “the Young’s modulus” should be changed to “Young’s modulus”. There is insufficient antecedent basis for this limitation in the claim.

As to claim 3, line 8 “the relation” should be changed to “a relation”. There is insufficient antecedent basis for this limitation in the claim.

As to claim 1, line 9 “the lower stiffness” it unclear whether this stiffness is "torsional stiffness" and/or "bending stiffness".

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moumene et al. (5,443,513) in view of St. Ville(6263252) further in view of Ramakrishna et al. (“Biomedical applications of polymer-composite material: a review”)and further in view of Draenert(5,824,083).

Moumene et al. teaches the claimed invention (claim 1) substantially as claimed including a method of designing and manufacturing an artificial joint stem with the use of a composite material comprising:

a. A first external layer, which is inserted and fixed in an insertion hole formed in a bone without filling cement, torsional stiffness thereof is increased as contacting an internal surface of said insertion hole is taught as the outer polymer skin or sheath which forms the shape of the implant and fills the space of a bone cavity in which the device is received(col. 3 lines 13-16);

b. A main structure layer, which is positioned in an inner side than said first external layer, bending stiffness thereof is increased is taught as the sheath or a outer wrap contains multiple layers of reinforced thermoplastic(col. 6 lines 5-6);

c. A core layer with lower stiffness than the main structure layer and the first external layer, which is positioned in an inner side than said main structure layer is taught as the core has a lower modulus than the sheath(col. 7 lines 41-43);

d. A most inner layer, which is positioned between the core layer and the main structure layer is taught as the filler region(col. 3 lines 60-61)

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- e. A computer is taught as computer(col. 6 line 15);
- f. Having said computer to reanalyze as changing said design condition if a result of said analysis fails to satisfy said design condition and designing and manufacturing said artificial joint stem using stem data based on said result of said analysis and said design condition if said result of said analysis satisfies said design condition is taught as computing design factor and transfer index. The design factor should be greater than one. The model evaluates many possible combinations of sheath fiber wrap orientation and sheath thickness until the desired transfer index, design factor and other properties are obtained. Possible combinations are adjustments along the using the finite element model to perform minor adjustments (modifying)when once all the factors are at desired values the composite is placed in a final mold which conforms the device to the desired final shape(col. 6 line 11 to col. 8 line 28).

Moumene et al. teaches the above listed details of the independent claim 1. however, Moumene et al. does not teach: an analysis involving an internal stress of said artificial joint stem, an adhesive stress of said artificial joint stem, a bone based on three dimension data indicating a structure of said bone made by using plural bone tomographic images and a design condition involving a form and stiffness of said artificial joint stem configured at least by one of said tomographic images and said three dimension image.

St. Ville teaches:

- a. An analysis involving an internal stress of said artificial joint stem is taught as stiffness of each layer is defined(col. 16 lines 44-46).

It would have been obvious to one of ordinary skill in that art at the time the invention was made or used to modify the teachings of Moumene et al. with the teachings of St. Ville

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because St. Ville teaches a method and apparatus for manufacturing objects(implants) having response to characteristics which are optimized for a desired applications or use. St. Ville uses a finite element model of bone geometry to defined stiffness. St Ville uses an iterative optimization techniques to calculate ideal stiffness properties at the elements of the finite element model. These matches as closely as possible to the bone stress with the implant which reduces bone shielding.

Ramakrishna et al. teaches

a. An adhesive stress of said artificial joint stem is taught as structural compatibility refers to the mechanical properties of the implant material, such as elastic modulus (o r E, Young's modulus) and strength, implant design (stiffness, which is a product of elastic modulus, E and second moment area, I) and optimal load transmission (minimum interfacial strain mismatch) at the implant /tissue interface(page 1190).

It would have been obvious to one of ordinary skill in that art at the time the invention was made or used to modify the teachings of Moumene et al. with the teachings of Ramakrishna et al. because Ramakrishna et al. teaches the materials of the implant. Using polymer-composite materials that can be changed and /or adjusted to produce different stress and strengths and elastic modulus to conforms to what the design of the implant needs.

Draenert teaches:

a. A bone based on three dimension data indicating a structure of said bone made by using plural bone tomographic images is taught as CT scanner takes images which can be stacked to produce a three-dimensional model of the bone(col. 3 lines 4—65);

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d. A design condition involving a form and stiffness of said artificial joint stem configured at least by one of said tomographic images and said three dimension image is taught as the design of the prosthesis component can ideally be fit(shape) into a medullary cavity and stiffness is selectively changed. By combining the images and analyzing the images a morphology and medullary of the bone as well as the strength can be determined for the design of the prosthesis(col. 2 lines 15-45).

It would have been obvious to one of ordinary skill in that art at the time the invention was made or used to modify the teachings of Moumene et al. with the teachings of Draenert because Draenert teaches a cement-free prosthesis. Draenert has a material selection according to the individual properties of a bone which allows the implant to closely resemble the bone in its properties of stress allowing the reduction of bone shielding.

As to claim 2, St. Ville teaches further comprising step of performing analysis including the internal stress of the bone analysis using the finite element is taught as a finite element of the normal bone geometry is created. The stiffness properties of each layer are then defined.(col. 16 lines 44-46).

It would have been obvious to one of ordinary skill in that art at the time the invention was made or used to modify the teachings of Moumene et al. with the teachings of St. Ville because St. Ville teaches a method and apparatus for manufacturing objects(implants) having response to characteristics which are optimized for a desired applications or use. St. Ville uses a finite element model of bone geometry to defined stiffness. St Ville uses an iterative optimization techniques to calculate ideal stiffness properties at the elements of the finite

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element model. These matches as closely as possible to the bone stress with the implant which reduces bone shielding.

As to claim 3,

Draenert teaches:

a. Wherein said tomographic image is a tomographic image, which is obtained by different transmission speed of the layers of the bone is taught as CT scanner has stacked images(tomographic)(col. 3 lines 43-46);

b. The density of every element of the bone based on the relation of the predetermined density and Young's modulus of the bone and the transmission speed is taught as bone density per unit area(col. 4lines 53-54).

It would have been obvious to one of ordinary skill in that art at the time the invention was made or used to modify the teachings of Moumene et al. with the teachings of Draenert because Draenert teaches a cement-free prosthesis. Draenert has a material selection according to the individual properties of a bone which allows the implant to closely resemble the bone in its properties of stress allowing the reduction of bone shielding.

St. Ville teaches:

a. a step of analyzing the internal stress of the bone as determining the Young's modulus is taught as stiffness properties are a function of Young's modulus(col. 16 lines 46-47).

It would have been obvious to one of ordinary skill in that art at the time the invention was made or used to modify the teachings of Moumene et al. with the teachings of St. Ville because St. Ville teaches a method and apparatus for manufacturing objects(implants) having response to characteristics which are optimized for a desired applications or use. St. Ville uses a

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finite element model of bone geometry to defined stiffness. St Ville uses an iterative optimization techniques to calculate ideal stiffness properties at the elements of the finite element model. These matches as closely as possible to the bone stress with the implant which reduces bone shielding.

As to claim 4, Moumene et al. teaches further comprising a step of forming as superposing the composite materials of the first external layer, the main structure layer, and the core layer by molding in a die is taught as once the core has been covered with predetermined number of layers; the composite is placed in a final mold which conforms to the desired final shape(col. 8 lines 25-28).

As to claim 5, Moumene et al. teaches further comprising a step of forming a model of said artificial joint stem or a forming die is taught as once the core has been covered with predetermined number of layers; the composite is placed in a final mold which conforms to the desired final shape(col. 8 lines 25-28).

As to claim 6, Draenert teaches further comprising a step of obtaining a material of the composite materials for the use in forming said artificial joint stem as controlling an automatic cutter based on the stem data is taught as material of the prosthesis can be selected according to the individual properties on the bone. CAD data sent to a milling unit(col. 2 lines 46-48 and col. 4 lines 21-30).

It would have been obvious to one of ordinary skill in that art at the time the invention was made or used to modify the teachings of Moumene et al. with the teachings of Draenert because Draenert teaches a cement-free prosthesis. Draenert has a material selection according

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to the individual properties of a bone which allows the implant to closely resemble the bone in its properties of stress allowing the reduction of bone shielding.

As to claim 7, Moumene et al. teaches further comprising a step of displaying a lamination layer position of the composite materials used in forming said artificial joint stem in a forming die of said artificial joint stem based on the stem data is taught as laminated layers 9col. 2 lines 4-7).

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHAD RAPP whose telephone number is (571)272-3752. The examiner can normally be reached on Mon-Fri 11:00-7:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Albert DeCady can be reached on (571)272-3819. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Albert DeCady/

Chad Rapp

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Supervisory Patent Examiner, Art Unit 2121

Examiner
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cjr